

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: AVANDIA MARKETING, SALES
PRACTICES AND PRODUCTS LIABILITY
LITIGATION**

:
:
: **MDL No. 1871**
: **No. 07-md-01871-CMR**
:

THIS DOCUMENT RELATES TO:

All Third Party Payor Actions

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**TWENTY-FIFTH REPORT AND RECOMMENDATION OF
THE SPECIAL MASTER AS TO A PROPOSED CASE MANAGEMENT ORDER FOR
ALL THIRD PARTY PAYOR ACTIONS**

The Special Master submits this Report and Recommendation recommending that the Court adopt the attached proposed Case Management Order for all Third Party Payor (“TPP”) cases pending before the Court.

BACKGROUND

The TPP Cases. Four TPP putative class actions are currently pending in this MDL.¹ These cases raise claims under the Racketeer Influenced and Corrupt Organizations Act (“RICO”), state consumer protection laws, and the doctrine of unjust enrichment. Plaintiffs contend that they relied on defendant’s allegedly false representations regarding the safety and efficacy of the Type 2 diabetes drug Avandia in deciding to include Avandia on their formularies, which led them to make greater

¹ *Allied Servs. Div. Welfare Fund v. GlaxoSmithKline et al.*, No. 09-730; *UFCW Local 1776 & Participating Employers Health & Welfare Fund v. SmithKline Beecham Corp. d/b/a GlaxoSmithKline et al.*, No. 10-2475; *United Benefits Fund v. GlaxoSmithKline LLC*, No. 10-5419; and *J.B. Hunt Transport Serv., Inc. et al. v. GlaxoSmithKline LLC, formerly SmithKline Beecham Corp. d/b/a GlaxoSmithKline*, No. 11-4013.

payments for Avandia prescriptions than they otherwise would have made.² Defendant moved to dismiss each case, and in October 2013, the Court issued an opinion and order denying defendant's motion, except as to plaintiffs' unjust enrichment claims.³ In denying defendant's motion, the Court held that plaintiffs had sufficiently pled both RICO injury and causation, and therefore, plaintiffs had standing under RICO to assert their false marketing claims.⁴

The Court found that plaintiffs plausibly alleged that, absent defendant's false marketing, plaintiffs would have included other, less expensive Type 2 diabetes drugs on their formulary, at substantial savings to plaintiffs, and this was a sufficient allegation of injury under RICO.⁵ The Court also held that plaintiffs alleged sufficient facts to prove causation under RICO, as plaintiffs contended that defendant's misrepresentations regarding the safety of Avandia increased the number of prescriptions for which plaintiffs were required to pay.⁶ The Court highlighted plaintiffs' allegations that pharmacy benefit managers "routinely rely upon existing scientific literature when making formulary decisions, and that *they did rely upon such literature when making formulary decisions about Avandia*. Therefore, Plaintiffs have adequately alleged that GSK misrepresented the safety of

² *In re Avandia Mktg. Sales Practices & Prods. Liab. Litig.*, 2013 U.S. Dist. LEXIS 152726, at *6-*7 (E.D. Pa. Oct. 22, 2013).

³ *Id.* at *43-*44. Defendant's motion to dismiss and the Court's ruling technically applied only to the first three TPP cases, as the fourth case (No. 11-4013) was not filed until June 20, 2011, more than seven months after defendant's motion was filed in the first three cases. The Court's analysis and ruling in the first three cases plainly apply to the fourth one, and all four are treated similarly for purposes of this Report and Recommendation.

⁴ *Id.* at *18-*29.

⁵ *Id.* at *18-*19.

⁶ *Id.* at *20-*22.

Avandia, and that these misrepresentations influenced the inclusion of Avandia on the formularies.”⁷

In rejecting defendant’s argument that plaintiffs’ causation theory was untenable because they continued to include Avandia on their formularies even after revelations in 2007 of alleged health risks of Avandia, the Court noted that “Plaintiffs may be able to prove that GSK’s earlier misrepresentations regarding Avandia’s risks were a proximate cause of formulary and coverage decisions made prior to 2007, as well as prescribing physicians’ decisions prior to 2007, notwithstanding their failure to remove Avandia from their formularies.”⁸ The Court also noted in this context “the potential difficulty in [plaintiffs] proving causation in the next stage of the litigation.”⁹ Finally, in addressing plaintiffs’ state consumer protection law claims, the Court reiterated that “Plaintiffs adequately allege that they relied upon GSK’s misrepresentations about Avandia’s safety in deciding to place Avandia on their formularies, as they allege that *they were reliant upon studies and marketing materials* which had been impacted by GSK’s alleged scheme to suppress publication of information about risks associated with Avandia use.”¹⁰

This Court certified its decision regarding plaintiffs’ RICO claims for interlocutory appeal under 28 U.S.C. § 1292(b), and in October 2015, the Third Circuit affirmed this Court’s ruling.¹¹ The Third Circuit pointed out that this Court noted that “the TPPs themselves relied upon [defendant’s] misrepresentations in making formulary decisions,” but that “plaintiffs may have difficulty in

⁷ *Id.* at *22 (emphasis added); *see also id.* at *26 (“Here, the TPPs have alleged that doctors relied upon GSK’s misrepresentations, and also alleged that *the TPPs themselves relied upon GSK’s misrepresentations when making formulary decisions.*” (emphasis added)).

⁸ *Id.* at *28.

⁹ *Id.*

¹⁰ *Id.* at *38 (emphasis added).

¹¹ *See In re Avandia Mktg. Sales Practices & Prods. Liab. Litig.*, 804 F.3d 633, 637, 646 (3d Cir. 2015).

proving causation at the next litigation stage because they did not restrict access to Avandia after the Nissen study [in 2007] publicized Avandia's heart-related risks.”¹² In agreeing with this Court's causation analysis, the court of appeals emphasized that the “conduct that allegedly caused plaintiffs' injuries is the same conduct forming the basis of the RICO scheme alleged in the complaint—the misrepresentation of the heart-related risks of taking Avandia that caused TPPs and [pharmacy benefit managers] to place Avandia in the formulary.”¹³ In addition, in rejecting defendant's arguments that the release in 2007 of information regarding Avandia's heart risks defeated plaintiffs' claims, the court noted the significance of plaintiffs' formulary decisions regarding Avandia and plaintiffs' knowledge of defendant's alleged fraud after the release of this information.¹⁴

Post-Remand Developments. Following the Third Circuit's decision, this Court held a status conference in January 2016 to discuss the management of these TPP cases, and on February 1, 2016, the Court issued Pre-trial Order No. 244, consolidating these cases for pre-trial purposes, appointing lead counsel and a plaintiffs' executive committee, and ordering the parties to submit a proposed case management order. After the parties submitted different proposed case management orders, the Court entered an order on February 25, 2016, referring to the MDL's Special Master the issue of development of a case management order governing these TPP cases.

The parties submitted proposals to the Special Master on March 7, 2016, and participated in a series of conference calls with the Special Master on February 29, March 10, and March 25, 2016, to discuss the different proposals. After consideration of the parties' proposals and supporting

¹² *Id.* at 637.

¹³ *Id.* at 644.

¹⁴ *Id.* (noting defendant's “two faulty assumptions . . . that plaintiffs did not change their coverage of Avandia in 2007,” and “that plaintiffs knew the full scope of GSK's alleged fraud based on the [2007] study”).

materials, the arguments of counsel, review of this Court's and the Third Circuit's opinions regarding defendant's motion to dismiss, and other relevant authorities, the Special Master proposed adoption of the Case Management Order submitted with this Report and Recommendation.

Defendant has accepted this recommendation. Plaintiffs objected only to the absence of two categories of discovery from the proposed Case Management Order: (1) Defendant's production of invoice level sales data concerning Avandia and other type 2 diabetes medicines, and (2) Rule 30(b)(6) depositions of defendant concerning the type and scope of data maintained by defendant regarding its Avandia-related marketing efforts and expenditures.¹⁵ Plaintiffs' objection to the absence of these two items is the focus of the discussion below.

Proposed Case Management Order. The proposed Case Management Order sets forth a schedule for initial discovery, with the possibility of further discovery after this initial phase of discovery is complete. The proposal also provides a briefing schedule for a motion for summary judgment on preemption grounds that defendant will file at an early stage of the discovery process,

¹⁵ Plaintiffs' proposal sought up to four Rule 30(b)(6) depositions related to defendant's creation and maintenance of databases containing information on: "[1] Invoice level sales data regarding Avandia or any other type 2 diabetes drug, including information on discounts, rebates, chargebacks, as well as any such data or documents acquired concerning Avandia or other Type 2 diabetes drug from IMS or other third parties. [2] Data concerning physician detailing, including call logs, regarding Avandia or any other type 2 diabetes drug and any such related data acquired from IMS or any other third party. [3] Data concerning marketing expenditures on Avandia or any other type 2 diabetes drug and any such related data acquired from IMS or any other third party. [4] Data or documents regarding patient switching within the therapeutic category, and any such data or documents acquired from IMS or any other third party. [5] Data or analysis concerning the relationship between marketing efforts and sales of Avandia, and any such data or documents acquired from IMS or any other third party. [6] Data regarding Avandia's placement on TPP formularies, and any such data or documents acquired from IMS or any other third party. [7] Data or documents concerning institutional marketing of Avandia, and any such data or documents acquired from IMS or any other third party. [8] Data or documents concerning Avandia's competitor drugs, and any such data or documents acquired from IMS or any other third party. [9] Data or documents regarding projected sales of Avandia, and any such data or documents acquired from IMS or any other third party. [10] Data or documents on patient use of Avandia."

after defendant provides plaintiffs with certain information related to the readjudication of the RECORD study.¹⁶ Pursuant to the proposal for initial limited discovery, defendant will provide plaintiffs with copies of all depositions taken in the *Santa Clara* case pending in this MDL and any documents reflecting defendant's communications with the plaintiffs regarding Avandia or other Type 2 diabetes medicines. All of this information will be produced in April and May 2016.

In roughly the same timeframe (*i.e.*, by June 1, 2016), plaintiffs will produce a number of documents and information related to such matters as their decisions regarding placement of Avandia or other medicines on their formularies, their payments for Avandia prescriptions, and any communications or other documents related to Avandia. In all, plaintiffs will produce documents or information in fifteen categories listed in Schedule A to the proposed Case Management Order. Finally, by June 1, 2016, plaintiffs will take depositions of any of defendant's employees who communicated with plaintiffs regarding Avandia or other type 2 diabetes medicines, and by the same date (or up to 45 days after production of the documents and information in Schedule A, if later), defendant will take a Rule 30(b)(6) deposition of each plaintiff.

The proposed Case Management Order requires the parties to assess the status of discovery after the initial discovery has been completed and, by July 15, 2016, meet and confer regarding the need for further discovery. The parties will notify the Court by July 31, 2016 whether they have agreed on the scope of any remaining discovery and, in the absence of such agreement, submit letters to the Court by the same date with their respective positions on this issue. The parties also will meet and confer by August 31, 2016 regarding a schedule for the remaining phases of these cases, including expert disclosures and discovery, class certification motions, dispositive motions,

¹⁶ RECORD is shorthand for Rosiglitazone Evaluated for Cardiovascular Outcomes and Regulation of Glycemia in Diabetes.

Daubert motions, and trial. The parties will notify the Court by September 15, 2016 whether they have agreed on a schedule for these items and, if no agreement is reached, submit to the Court their competing proposals for the remaining schedule by the same date.

DISCUSSION

Plaintiffs contend that they will meet their burden of proving causation in these cases through a regression analysis that relies on national sales and marketing data to demonstrate the link between defendant's marketing efforts and the economic loss that plaintiffs suffered from having Avandia on their formularies and from charging more for Avandia than they would have charged if they were aware of its purported health risks. The regression analysis also will be used to show the extent of those economic losses. Plaintiffs argue that, to undertake this analysis, they need the national sales and marketing data regarding Avandia that they seek from defendant.

In their March 7, 2016 submission to the Special Master, plaintiffs argued that this information "is necessary for purposes of establishing causation on a class wide basis," but they later argued that, regardless whether their proof proceeds on an individual or class-wide basis, they are entitled to rely on national sales and marketing data to prove causation. In either case, plaintiffs contended, their experts would use the national sales and marketing data to prepare a regression analysis that would demonstrate that defendant's allegedly false marketing efforts caused an increase in the number of Avandia prescriptions. The regression analysis also would calculate the proportion of Avandia prescriptions caused by defendant's marketing efforts, which would be used to determine the losses suffered by plaintiffs.

The starting point for analysis of plaintiffs' request for discovery from defendant of national invoice level sales data and information on defendant's national marketing efforts and expenditures is this Court's and the Third Circuit's opinions regarding defendant's motion to dismiss. In those opinions rejecting defendant's arguments for dismissal of plaintiffs' RICO claims, neither court

indicated that plaintiffs could prove injury or causation through aggregate data or statistical proof. To the contrary, the language of both courts' opinions evinces an assumption that plaintiffs would have to prove these key elements of their cases through the traditional vehicle of individualized proof. In particular, both courts focused on the individual plaintiffs' reliance on defendant's alleged misrepresentations about Avandia and the individual plaintiffs' own decisions regarding placement of Avandia on their formularies. While the issue of statistical proof was not squarely presented by defendants' motion to dismiss, this Court and the Third Circuit offered no indication that plaintiffs could prove their RICO case through aggregate proof, rather than by offering evidence that each of them relied on defendant's representations regarding the safety of Avandia and that defendant's marketing efforts caused each plaintiff to place Avandia on its formulary.

The initial discovery that is covered by the proposed Case Management Order will provide the plaintiffs with the information necessary to litigate these issues, including whether plaintiffs relied on defendant's alleged misrepresentations regarding the safety and efficacy of Avandia and whether those representations led to increased expenditures for plaintiffs. The Special Master does not believe that defendant should have to produce documents regarding nationwide sales or disclose detailed information about its tracking of nationwide marketing efforts and expenditures when the courts that have opined on plaintiffs' claims thus far have assumed plaintiffs would prove those claims through individualized proof.

This Court's and the Third Circuit's focus on individualized proof is perhaps not surprising, given the lack of precedent within the Third Circuit supporting the use of aggregate proof to demonstrate injury and causation in a RICO case. As discussed below, the primary case relied upon by plaintiffs in arguing that they can rely on such proof is not binding on this Court, as it is a First Circuit decision. Moreover, some courts within this circuit have expressly rejected the use of statistical proof in lieu of individual proof in cases similar to these.

For example, in a 2009 decision granting defendants' motion to dismiss third party payors' RICO claims alleging illegal marketing of prescription medicines, Judge Chesler of the District of New Jersey held that the plaintiffs "may not prove causation by way of generalized allegations and aggregate proof."¹⁷ The plaintiffs in that case had argued that they could "demonstrate causation through expert testimony and a statistical analysis of [defendant's] sales data."¹⁸ Judge Chesler rejected this argument.¹⁹ While, as Judge Chesler acknowledged, some courts have allowed such statistical proof in lieu of individualized proof, many other federal courts have rejected the use of aggregate data or statistical analyses to prove RICO claims.²⁰

As noted, plaintiffs rely on the First Circuit's rulings in *In re Neurontin Marketing & Sales Practices Litigation*²¹ to argue that they can prove their RICO claim through the use of aggregate data and a

¹⁷ *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 U.S. Dist. LEXIS 58900, at *86-*89 (D.N.J. July 10, 2009).

¹⁸ *Id.* at *84-*85.

¹⁹ *Id.* at *86-*89.

²⁰ See, e.g., *Kaiser Found. Health Plan, Inc. v. Pfizer, Inc. (In Re Neurontin Mktg. & Sales Practices Litig.)*, 748 F. Supp. 2d 34, 92 (D. Mass. 2010) ("Defendants correctly point out that proof of fraud on the market in the aggregate has not been embraced in the case law as a basis for proving causation in individual cases."); *Guardian Life Ins. Co. of Am. v. Pfizer, Inc. (In re Neurontin Mktg. & Sales Practices Litig.)*, 677 F. Supp. 2d 479, 494 (D. Mass. 2010) ("trial courts have almost uniformly held that in a misrepresentation action involving fraudulent marketing of direct claims to doctors, a plaintiff TPP or class must prove through individualized evidence that the misrepresentation caused specific physicians, TPPs, or consumers to rely on the fraud, and cannot rely on aggregate or statistical proof") (citing four district court cases and one court of appeals case). As discussed below, the First Circuit reversed the district court in the *Neurontin* case to the extent the district court rejected the use of statistical analysis as proof of causation and economic loss. These cases are cited, however, because they accurately note that many courts have rejected the use of statistical analysis in lieu of individualized evidence as proof of causation.

²¹ The court issued a number of decisions on the same day, addressing various district court rulings in the *Neurontin* case. See 712 F.3d 60 (1st Cir. 2013) [*"Harden Mfg. Corp."*]; 712 F.3d 51 (1st Cir. 2013) [*"Aetna, Inc."*]; 712 F.3d 21 (1st Cir. 2013) [*"Kaiser Found. Health Plan, Inc."*]. The most extensive opinion, *Kaiser Foundation Health Plan, Inc.*, was an appeal from a judgment entered following a jury verdict for Kaiser.

regression analysis that would demonstrate that (and the extent to which) defendant's marketing efforts caused plaintiffs' economic injuries. While acknowledging that some courts had rejected the use of aggregate data in RICO cases, the First Circuit endorsed the use of such data and statistical analyses to prove causation, "especially where the plaintiffs allege a 'quantity effect' rather than an 'excess price' theory."²²

In its most extensive discussion of the issue, in the appeal from the judgment for Kaiser, the court noted that plaintiff's primary causation evidence was the expert testimony of Dr. Meredith Rosenthal, who claimed that her analysis "established causation by performing a regression analysis on sales information against promotional spending on detailing, professional journal advertising, and the retail value of samples, while controlling for other variables."²³ The court held that this use of a statistical analysis based on national data (rather than data specific to plaintiff Kaiser) was reasonable and permissible.²⁴ While the *Neurontin* decisions support plaintiffs' claim here that they are entitled to use national sales and marketing data, and statistical analyses, to prove causation and injury, for a number of reasons, the Special Master does not believe the Case Management Order should require defendant to produce such information (or produce Rule 30(b)(6) witnesses on these topics) at this time.

First, this Court's decision denying defendant's motion to dismiss plaintiffs' RICO and state consumer protection law claims, as well as the Third Circuit's decision affirming this Court's ruling, do not contemplate plaintiffs proving their claims through aggregate data. To the contrary, both opinions appear to assume that plaintiffs must demonstrate their individual reliance on defendant's

²² *Harden Mfg. Corp.*, 712 F.3d at 69.

²³ *Kaiser Found. Health Plan, Inc.*, 712 F.3d at 30.

²⁴ *Id.* at 44-45.

alleged misrepresentations regarding Avandia's safety and that they must prove an individualized causal link between defendant's marketing and promotional activities and plaintiffs' own decisions regarding Avandia. Whether plaintiffs should be allowed to prove their case through national data and regression analysis rather than individualized evidence is for the Court to decide, not the Special Master.

Second, plaintiffs have pointed to no binding precedent from the Third Circuit or the Supreme Court allowing the use of aggregate data and statistical analysis to prove RICO causation and injury.²⁵ If this case were being litigated in a district within the First Circuit, defendant would be hard pressed to argue that the *Neurontin* decisions did not apply and that plaintiffs could not use national data and statistical analysis to prove their case. But it is being litigated in a district within the Third Circuit. The Special Master does not believe that defendant should be required at this time to produce nationwide data in support of a causation theory that has yet to be accepted by this Court in this case or by the Third Circuit in any similar case and has been specifically rejected by many courts.

²⁵ Plaintiffs point to the Supreme Court's recent decision in *Tyson Foods, Inc. v. Bouaphakeo*, 2016 U.S. LEXIS 2134 (Mar. 22, 2016), as support for their argument, but *Tyson Foods* is easily distinguishable. First, *Tyson Foods* was an overtime pay class action under the Fair Labor Standards Act, not a RICO case, with very different requirements of causation, injury, and damages. *Id.* at *6. Second, in approving the use of expert testimony that relied on aggregate data to estimate the amount of uncompensated time each employee worked, the Court specifically cautioned that it was not establishing "general rules governing the use of statistical evidence, or so-called representative evidence, in all class-action cases." *Id.* at *13, *20. Third, *individualized* data on the amount of time each employee spent at his or her workstation and the amount of time for which the employee was compensated for donning and doffing work gear *was* used to determine the amount of uncompensated work each employee did, so *Tyson Foods* was not a case in which statistical analysis was used as a complete substitute for individualized proof. *Id.* at *13. Finally, a key factor in the Court's approval of aggregate data was the defendant's failure to maintain records necessary for the individual class members to prove their case; the representative sample used by plaintiffs' expert filled "an evidentiary gap created by the employer's failure to keep adequate records." *Id.* at *22.

Third, even without the detailed national sales and marketing data that plaintiffs seek, they will have access to other information on these topics that already has been produced in this MDL, as well as documents and witnesses on the topic of defendant's marketing to the plaintiffs themselves. Finally, plaintiffs can seek national sales and marketing data on Avandia and other type 2 diabetes medicines from third parties. Indeed, the great majority of the data used by the expert witness for her regression analysis in the *Neurontin* litigation on which plaintiffs rely came from third parties and not from the defendant in that case.

As the district court explained in one of its *Neurontin* opinions, Dr. Rosenthal "used 'gold standard' national data on Neurontin and other anti-epileptic drugs from IMS Health and Verispan."²⁶ Dr. Rosenthal used some discovery information obtained from the defendant in *Neurontin* for her analysis, but the courts' opinions, her trial testimony in the *Kaiser* case, and her expert report all make clear that the great bulk of the data for her regression analysis came from third parties and not the defendant. For example, she testified that there "were two important pieces of information, fundamental pieces of information from my analysis, . . . the first one would be the sales of Neurontin, and, in particular, I look at the number of prescriptions of Neurontin, and *those data come from this organization I mentioned earlier, IMS Health, which is a consulting company. Some pieces of data also come from a company called Verispan, which is another data and consulting company well known in the pharmaceutical industry. All of these companies produce data for the industry that is used for strategic and competitive purposes, so those are the quantities that I use in my model.*"²⁷

²⁶ *Kaiser Found. Health Plan, Inc.*, 748 F. Supp. 2d at 68; *see also Kaiser Found. Health Plan, Inc.*, 712 F.3d at 44 ("Dr. Rosenthal used data that was prepared by independent consulting companies").

²⁷ *Kaiser Found. Health Plan v. Pfizer, Inc. (In re Neurontin Mktg., Sales Practices, and Prods. Liab. Litig.)*, No. 04-10981-PBS, Trial Tr. at 117:11-23 (Mar. 5, 2010) (emphasis added; paragraph break omitted).

Dr. Rosenthal explained that in addition to the prescription information that she obtained from third parties, she also used in her regression analysis price information and data on promotional spending from these third parties.²⁸ The latter category—marketing and promotional data— included the retail value of samples, journal advertising expenditures, and detailing spending,²⁹ which Dr. Rosenthal contended was the most important promotional information for her regression analysis.³⁰ Thus, it appears that plaintiffs in these cases can obtain from third parties the national sales and marketing data they claim to need to prove causation and injury, as the plaintiffs did in the *Neurontin* litigation.

In short, on the current record and for the reasons set forth above, the Special Master does not believe that, at this time, defendant should have to produce the national sales data plaintiffs seek or Rule 30(b)(6) witnesses to testify on the detailed list of promotional information identified by plaintiffs.

CONCLUSION

The Special Master recommends that the Court adopt the proposed Case Management Order attached to this Report and Recommendation.

/s/ Bruce P. Merenstein

Bruce P. Merenstein, Special Master

Dated: April 4, 2016

²⁸ *Id.* at 118:12-119:3; *see also id.* at 120:9-122:14 (explaining use of National Disease and Therapeutic Index).

²⁹ *Id.* at 118:23-119:3; 135:17-22.

³⁰ *Id.* at 137:15-139:6.

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CERTIFICATE OF SERVICE

I, Bruce P. Merenstein, hereby certify that on April 4, 2016, I caused to be electronically filed the foregoing **Twenty-Fifth Report and Recommendation of the Special Master As to a Proposed Case Management Order for All Third Party Payor Actions**. Through the Court's ECF system, this document is available for viewing and downloading.

/s/ Bruce P. Merenstein

Bruce P. Merenstein